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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,623	11/20/2003	Santosh Misra	7013-67324	3643

7590 07/14/2005

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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,623	MISRA ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-23,25 and 28* is/are rejected.

7)☒ Claim(s) *24,26 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/03,2/13/04*. 11/8/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it is not directed to the claimed invention. Correction is required. See MPEP § 608.01(b).

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

4. Applicant is advised that should claim 14 be found allowable, claim 15 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. In the instant claims, the subject matter encompassed by claims 14 and 15 appear to be identical, because plants do not naturally comprise a nucleic acid molecule encoding a temporin peptide, which by its nature is cationic. The specific limitations in claim 15 appear to be implied in claim 14. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14, 15, 20, 21, 22, 23, 25 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a transgenic plant comprising a recombinant nucleic acid molecule encoding a temporin peptide. Applicant also claims said transgenic plants wherein said nucleic acid molecule encodes a peptide having one or more conservative amino acid substitutions or that shares at least 90% or 95% sequence identity to SEQ ID NO: 17 (temporin G).

Applicant describes nucleic acid molecules encoding temporins A, B, C, D, E, F, G, H, K, and L in SEQ ID NOs: 18, 19, 20, 21, 22, 23, 17, 24, 25 and 26 respectively.

Applicant does not describe nucleic acid molecules encoding temporins as broadly claimed, because Applicant states that the limitation "temporin" encompasses "A variant temporin will typically 10 share at least 40% amino acid sequence identity with a naturally occurring temporin peptide (such as the one shown in SEQ ID: 17)" (page 11, lines 9-11 of the specification). Applicant does not describe such variants,

nor does Applicant describe nucleic acid molecules encoding fragments of polypeptides described by SEQ ID NOs: 17-26 (see specifically claim 22).

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed.

See, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case, neither the art nor Applicant describes structural characteristics of temporins that correlate with their function.

7. Claims 14-23, 25 and 28 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a transgenic plant transformed with a nucleic acid molecule encoding the polypeptide of SEQ ID NO: 18, does not reasonably provide enablement for a transgenic plant transformed with a nucleic acid molecule encoding any temporin, fragment thereof or variant thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim a transgenic plant comprising a recombinant nucleic acid molecule encoding a temporin peptide. Applicant also claims said transgenic plants wherein said nucleic acid molecule encodes a peptide having one or more conservative amino acid substitutions or that shares at least 90% or 95% sequence identity to SEQ ID NO: 17 (temporin G).

Applicants teach nucleic acid molecules encoding temporins A, B, C, D, E, F, G, H, K, and L in SEQ ID NOs: 18, 19, 20, 21, 22, 23, 17, 24, 25 and 26 respectively. In addition, Applicants teach a transgenic plant transformed with a nucleic acid molecule encoding temporin A (pages 27 and 32).

Applicants do not teach plants transformed with nucleic acid molecules encoding temporins as broadly claimed, because Applicants state that the limitation "temporin" encompasses "A variant temporin will typically 10 share at least 40% amino acid sequence identity with a naturally occurring temporin peptide (such as the one shown in SEQ ID: 17)" (page 11, lines 9-11 of the specification). Applicants do not teach how to make and use such variants, nor does Applicants teach how to make and use nucleic acid molecules encoding fragments of polypeptides described by SEQ ID NOs: 17-26 (see specifically claim 22).

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has provided limited guidance on how to make and use transgenic plants comprising a recombinant nucleic acid molecule encoding a temporin peptide as broadly claimed. Neither the art at the time of the invention, nor Applicants provide guidance on how to make and use fragments or variants of know temporin peptides as required to make and use the claimed transgenic plants. The art teaches that temporins D and H have negligible effects on pathogenic bacteria (see Barra *et al*, U.S. Patent 6,301,176, column 7). The art also teaches that temporins C, E and K are inactive forms (see Simmaco *et al* 1996, European Journal of Biochemistry 242:788-792, see specifically page 791, right column). Simmaco *et al* also teach that temporins have a minimal requirement of 13 amino acid residues, hence the "fragments thereof" at claim 22 does not appear to be enabled given the teachings of the art. Hence, given Applicant's limited guidance, the nature of the claimed invention, the breadth of the claims and the teachings of the art at the time of Applicant's invention, it would have required undue trial and error experimentation by on of skill in the art at the time of the invention to make and use plants transformed with a nucleic acid molecule encoding a temporin peptide as broadly claimed.

Allowable Subject Matter

8. Claims 24, 26 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

9. The claims are free of the prior art, which neither teaches nor suggests plants transformed with nucleic acids encoding temporin peptides.

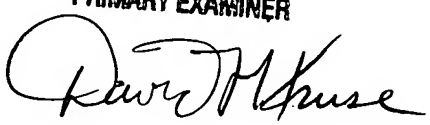
10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (571) 272-0745. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
8 July 2005

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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